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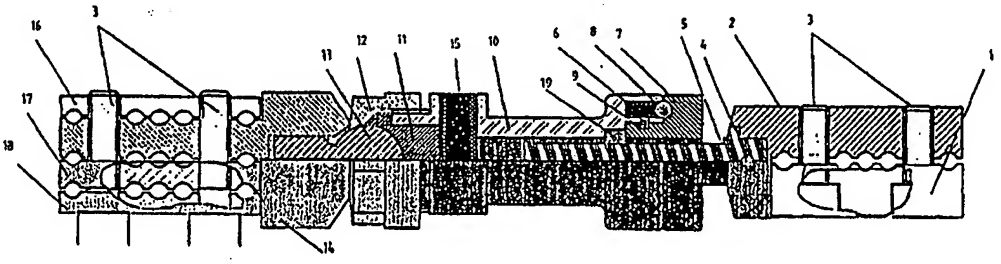
(54) Title: STABLE DYNAMIC AXIAL FIXATOR



(57) Abstract

Stable Dynamic Axial Fixator is a ball–socket type, monoarticulated which can be cancelled for the stability, external fixator used in orthopaedic and traumatological surgery. This fixator was designed for a new and unique application technique which increases the stability and also minimise the need of X–ray usage. The additional advantages were superposition of fixator on X–ray image was minimised, the risk of loosening of the pin was also minised by decreasing the weight, and hospitalisation time was reduced. To increase the stability of the articulation, "body contact of the clamp" was achieved at the final position of the application and also the surgeon can cancel the articulation (if not need) by sliding the clamp on the articulation globe (13). Secondly to increase the stability the height of the eccentric pin was reduced. By this way the load arm can be shortened, thus the surgeon can fix the articulation globe (13) with more force, which increases the stability. The polyplanar clamp can fix the fragments in different combination and in different angle without using articulation. Also it can translate the fragments of the bone. By the means of new distraction–compressing unit the surgeon and the patient can easily distract or compress the fragments of the bone only by turing the extension nut (7) in one direction up click sound was heard. No other work is needed to stabilise or anything else. So adaptation time of the patient and the hospitalisation time was reduced.

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STABLE DYNAMIC AXIAL FIXATOR

This invention is related to an external fixator in type of removable ball-socket articulated dynamic axial fixator used in treatments of fractured, deformed and shortness of long bones in the branches of Orthopaedics and traumatology of the field of medicine.

External fixators used in medicine are classified in several major groups. Sub-groups where that invention falls, and some examples of works under patent belonging to such groups are as follows:

a-Inarticulated: Orthofix External Fixer

b-Double-articulated ball-socket type: Orthofix External Fixator

c-Double articulated hinged type: Wagner External Fixator, Howmedica monotube External Fixator

In fixators of this type, generally there are clamp parts which would hold both epiphysis separately, two articulation pieces adapted to clamps which provide redressing and adaptation of fracture, body illustrating the length of device and elongation rate thereof, distraction units ensuring extension and shortening.

As distraction units achieve extension and shortening actions in the body as an unit annexed to body, and in the manufacture of this unit certain metal alloys being used with higher resistance and higher density but having less perviousness against X-rays, renders more difficult to fix the articulation by X-ray film. For these reasons, excessive use of X-ray device is required to be able to do articulation fixation,

and thus, both patient and doctor are being exposed to X rays more. Anyhow, the risk of fractured reposition loss is still higher due to insufficient articulation fixation. In addition thereto, super-position event is more frequently encountered in X-ray films.

As annexed unit which has been mounted over body and which provides the modification of body length through fitting its parts one into another, could change the length with the help of the keys and by exercising force, this process which renders difficulties of patient's use, cause of delay for adaptation of the patient to device, and extends the time of staying in hospital.

Controlled dynamization could not be achieved due to device length could be changed by the rate of force applied to distraction unit, and the risk of progression in shortness is increased consequently.

Usage of devices in sizes more than one is necessary due to amount of distraction-compression is limited. Weights of annexed devices and additional unit lead to loosening of nails during usage.

Articulation angle in existing fixators is maximum 22° and fixator is not sufficiently functional in fractured repositioning due to insufficiency of articulation angle.

In this connection, purpose of this invention is to provide the fixator which would be used in treatments of fractured, deformed and shortness of long bones at orthopaedics and traumatology being effective to fix the bone in a straight and

stable manner until the completion of welding, and being capable of doing angularity and controlled dynamization, if needed, further its being functional as much as possible, having enough spaciousness for articulation movement and high modularity, stable, would not cause any reposition loss during application and within time; light, hygienic, pervious for X-rays in sufficient degree, capable for easy application, smoothly acceptable by patient and easily usable.

Fixator which is developed for attaining the objectives of this invention is shown in enclosed illustrations which reflect following outlooks;

Figure 1- Articulation fixation by using fixator on fractured bond.

Figure 2- Complete section of polyplanar clamped fixator.

Figure 3- Complete section of monoplanar clamped fixator.

Figure 4- A view from a section of polyplanar clamp and articulation globe.

Figure 5- A view from a section monoplanar clamp and of clamp cover.

Figure 6- A view of removable articulation from a section.

Figure 7- A section of distraction unit.

Figure 8- A view of sliding clamp cover.

Parts in figures have been numbered one by one, and the descriptions corresponding to these numbers are given below:

(1) Monoplanar Clamp Cover

(2) Body of Monoplanar Clamp Cover

(3) Bolt

(4) Pin

(5) Extension bolt

(6) Press spring

(7) Extension nut

(8) Ball

(9) Segment

(10) Tightening cleat

(12) Tightening nut

(13) Articulation globe

(14) Polyplanar clamp body

(15) Eccentric Pin

(16) Polyplanar Clamp Bottom Cover

(17) Polyplanar Clamp Intermediary part

(18) Polyplanar Clamp Upper Cover

(19) Derotation Pin

Figure 1 is the outlook of fixator in the position where polyplanar clamps have been fixed on bone through its special nails (Figure 4).

As is seen in Figures 2 and 3, fixator body (10) is telescopic, and works also by moving within extension bolt (5). It is possible to use the body in large, middle and small sizes by selecting extension bolts in different longitudes.

Polyplanar clamp, as is seen in Figures 2 and 4, is composed of two bolts (3), polyplanar clamp body (14), polyplanar clamp bottom cover (16), polyplanar clamp intermediary part (17) and polyplanar clamp upper cover (18), and is allowed to place nails in different plans and various combinations. Fixator with inarticulated polyplanar clamp could be used in bones having a broad clinging surface (like metaphase), angularity of fractured and translation thereof could also be corrected through this clamp.

Monoplanar clamp as seen in Figures 2, 3 and 5, containing Monoplanar Clamp cover (1), Monoplanar clamp body (2) and 2 bolts (3) ensures the placement of nail in single plan, and could be used articulated or inarticulated manner according to requirements.

Figure 6 illustrates removable articulation. When needed, by loosening bolt on the clamp (3) space between clamp and tightening nut is broadened, and by turning eccentric pin (15) tightening cleat (11) is loosened and the globe (13) is become idled. Thus, clamp could be given such angularity around a circle of 360° to a direction up to 30° from the center, so the angle of articulation is being increased and therefore device becomes more functional. In order to fix in desired angle, firstly tightening nut (12) is tightened for taking in the slack of articulation. Thereafter, eccentric pin (15) is tightened with "L-alian" wrench by maximum force. Then, clamp is made to be slided on the body of globe (13) until taking in the slack of articulation, and thus clamp body is leaned against tightening nut. In this way, load is being transferred directly to the body

and articulation could be removed or insufficiency position of articulation in angular fixation could be eliminated. Through taking in the slack of articulation by tightening nut and reducing of height of eccentric pin (15) down to maximum 0.5 mm load arm is shortened, more tightening of globe is ensured, and stability is increased by sliding of eccentric in the course of time with a counter-screw applied to eccentric. Distraction-compression share has also been increased by removal of articulation. By the grace of removalableness of articulation, problem of reduction loss due to articulation insufficiency is also eliminated and furthermore, stability is increased. Removableness of articulation causes also to ease production and cost decrease as well. Thus, "removable ball-socket type articulated external fixators" has been added to external fixators as a new sub-group. This method could be used in both clamps.

Figure 2 is an outlook of distraction unit. Distraction unit consisting of extension bolt (5), pressing spring (6), extension nut (7), ball (8), segment (9) and derotation pin (19) is placed within body. Therefore, annexed unit which was using for the same purpose has been removed, and in this way, perviousness of device for X-rays is increased and radioscopy process becomes easier. At the same time, the risk of loosening in nails is also reduced along with decrease of super-position risk and the weight of device. If extension nut (7) is turned clockwise one tour, then the system is being extended 1.2 mm. Meanwhile, spring ball is seated into its three separate sockets with equal intervals placed onto extension nut with a "click"

sound, an warns the user, as well as ensures rotation stability. Here, each "click" sound corresponds 0.4 mm. For compression, these steps would be repeated vice versa. So, by presenting easiness in use, adaptation of patient becomes easier.

Figure 8 is an outlook of sliding clamp cover. Monoplanar clamp cover (1) is slided towards outside by loosening external bolt (3) for smooth application of nail to the bone. After fractured reduction is achieved, external screw is tightened. After internal nail is placed into the bone, cover (1) is locked by being slided. This practice provides easiness in technical usage. In Figure 1, the locked position of sliding clamp cover and the area of movement of cover with the help of bolt hole design could be seen.

Invention could reliably be used in long bones of extremities. As device has been designed in a modularly structure and could be produced in different sizes, suitable fixator is selected as to the kind, location and length of bone. If articulated fixator is preferred, articulation in flat bones is hold firstly straight and closed, distraction-compression share is adjusted. Long bone is rather taken to traction. Nails at both farthest ends of fixator will be placed into bone at 90° under sterile conditions. Thus, fractured re-position in front-rear plan is being ensured. In second step, nail is placed at the same plan with first nail and parallel thereto into the hole nearest fractured or farthest hole from previous nail. If while placing the nail, central line of bone is not balanced, fractured bone is pulled downward or upward, and central line is so matched. Same process is applied to opposite side and

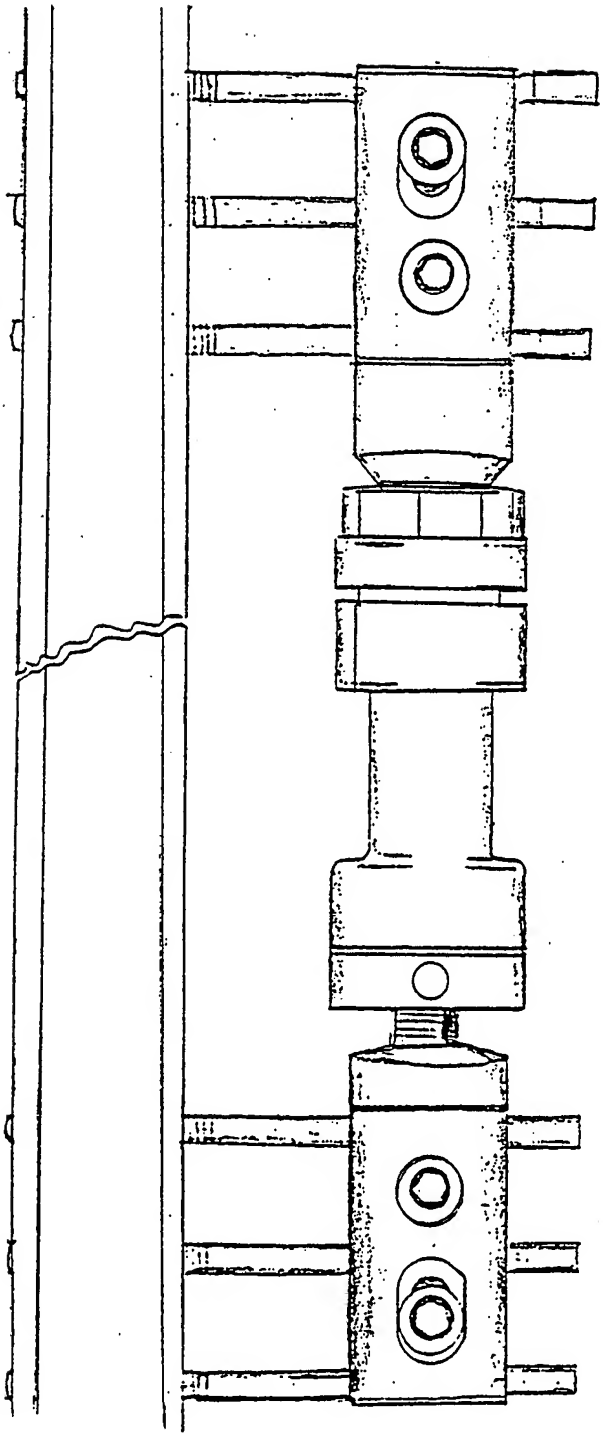


Fig. 1

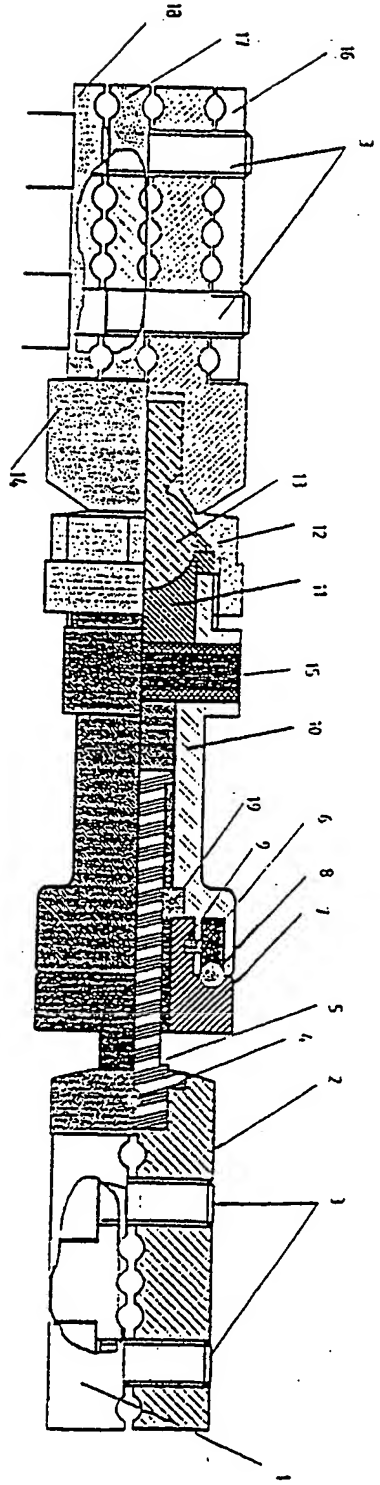


Fig. 2

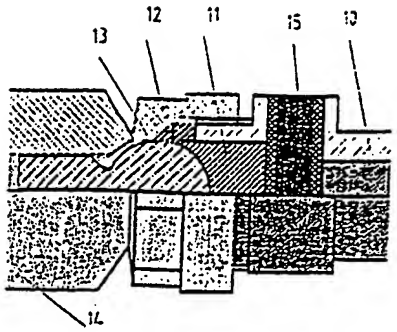


Fig. 6

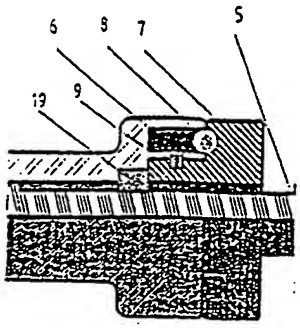
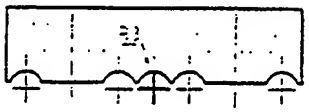
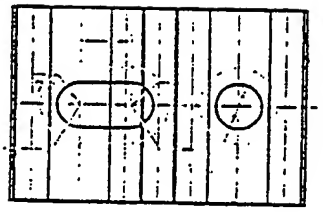
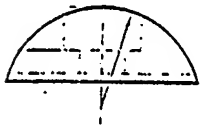


Fig. 7

Fig. 8







INTERNATIONAL SEARCH REPORT

Inter nal application No.
PCT/TR 98/00018

A. CLASSIFICATION OF SUBJECT MATTER

IPC^6: A 61 B 17/64

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC^6: A 61 B 17/60, 17/64

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPI, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96/05 777 A1 (ORTHOFIX) 29 February 1996 (29.02.96), totality; especially fig.1,2,5,7,12; abstract; claims 1,2,6,7.	1
X	US 4 312 336 A (G. DANIELETTO et al.) 26 January 1982	2
A	(26.01.82), fig.2,10,13; column 2, line 67 - column 3, line 18; column 5, lines 14-17,50-64.	4,5
A	GB 2 168 255 A (ORTHOFIX) 18 June 1986 (18.06.86), totality.	2-5
A	DE 41 39 700 A1 (R. STURTZKOPF et al.) 08 April 1993 (08.04.93), totality.	2-5

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
28 December 1998 (28.12.98)	13 January 1999 (13.01.99)

Name and mailing address of the ISA/	Authorized officer
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Facsimile No. 1/53424/535	Telephone No. 1/53424/349

Form PCT/ISA/210 (second sheet) (July 1998)

The document WO 96/05 777 A1 relates to a trochanter splint comprising a pair of clamps (2,3) with their respective longitudinal axes (a,b), one of which is designed for the movable locking of a first group of bone bolts (V) inserted into the mass of the trochanter, the other for the movable locking of a second group of bone bolts (W) inserted into the proximal diaphysis of the femur. The two clamps are connected together in a side-by-side position by an intermediate connecting member (4).
A first securing unit for selectively immobilising the angle of divergence between the longitudinal axes, and second locking unit for selectively immobilising the angle of rotation of at least one of the clamps about its own longitudinal axis are provided. The intermediate member comprises a central body connected to clamps by a pair of rotatable joints with corresponding axes of rotation which are at right angles. The bolts of the clamp along the trochanter can be immobilised along convergent lines, the joint between the two clamps having one or more frusto-conical contact surfaces and the femoral clamp being subdivided into two parts which can be orientated about its own axis.

The document US 4 312 336 A relates to an external fracture setter consisting of a centre telescopic part with each end fitted with a clamp for a group of locating pins. Each of the two telescopic parts is connected to a compression and extension member. The two centre part components (10,11) are connected to the clamps (17) by ball joints (16,18). The clamp settings and the positions of the components (10,11) are locked in place by arresters. The compression and extension members (14) are releasably connected to the components. The ball joints (16,18) are secured to the clamp jaws (21) via a collar (19) and a rod (20).
The ball joints have a threaded ring (22) so that the clamp jaw (21) is fixed to the ball and works with an adjustable jaw (27) to hold the pins. Compression and extension are provided by hollow cylinders (37,38) with carried upright bolts (13,13') set to the ends of the telescope (10,11). Each bone pin has a cylindrical shank and tapered core (29) with spiral constant pitch outer thread so that the shank locates in the clamp sockets (26).

The document GB 2 168 255 A relates to an external orthopaedic instrument for securing parts of fractured bones. The instrument has a adjustable-length central body (10) with two pin-holders (15,17) at the ends attached to it by ball-joints (16,18) whose centres are on its lengthwise axis, while locks secure the holders at the desired angles. A jack (11) acts at the body ends.
The body is in three or more parts (12,13,14) movable in relation to each other with a telescoping action, while axial guides (30,32,34,36) between the parts prevent rotation and are lockable. Eccentric tubular pins (21,21') turn freely in the end parts (12,14) and accommodate the pins of the jack mechanism.

The document DE 41 39 700 A1 relates to an external clamp for bone fragments, which also forms a connection with screws inserted in the fragments, has a cross member (1) at the top of an elongated stem consisting of sections which include two ball joints (15). At top and bottom are jaws clamped together by screws (7) and with rounded recesses across their clamping surfaces, forming openings (10,12) for the screws to be clamped.
The jaws have borings arranged so that the canal inlet openings for the bone screws are arranged in a triangle. The setting of the ball joint (15) is effected by a tubular eccentric pin (28,29), by which an engaged ball joint seat (30) is jammed against the ball joint (15).

INTERNATIONAL SEARCH REPORT

Inte onal application No.
PCT/TR 98/00018

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